DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 28, 2015

Facet-Link, Incorporated
% Ms. Janice M. Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K150223
Trade/Device Name: Facet-Link Stabilization Platform
Regulatory Class: Unclassified
Product Code: MRW
Dated: January 30, 2015
Received: January 30, 2015

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150223

Device Name

Facet-Link Stabilization Platform

Indications for Use *(Describe)*

The Facet-Link Stabilization Platform is intended to stabilize the spine as an aid to fusion through immobilization of the facet joints. The system is indicated for use with bone graft, at single or multiple levels, from C2 to S1 (inclusive) for the Facet Screws and L3 to S1 (inclusive) for MINI and HEMI devices. The Platform is indicated for the treatment of any or all of the following:

1. Spondylolisthesis.
2. Degenerative disc disease (DDD) as defined as back pain of discogenic origin as confirmed by radiographic studies.
3. Degeneration of the facets with instability.

The Facet-Link Facet Screw System is indicated for treatment of any or all of the following:

1. Pseudoarthrosis and failed previous fusion;
2. Spondylolisthesis; and
3. Degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies.

Type of Use *(Select one or both, as applicable)*

[x] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Facet-Link's Stabilization Platform

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Facet-Link, Inc.
101 Roundhill Drive, 2nd floor
Rockaway, NJ 07866

Phone: 973-627-4171
Facsimile: 973-718-4672
Contact Person: Massimo Calafiore
Date Prepared: April 6, 2015

Device Information

Trade Name: Facet-Link Stabilization Platform
Common or Usual Name: Facet Screw Spinal Device System
Classification: Unclassified
Product Code: MRW

Predicate and Reference Devices:

Primary Predicate Device: Facet-Link, Inc.'s Facet Screw System (K123497)
Reference Devices: Medtronic Sofamor Danek's TOWNLEY Transfacetpedicular Screw Fixation System (K013829); Medtronic Sofamor Danek's TSRH Spinal System (K081080); Spinal Concepts Inc.'s Speedlink Transverse Connector (K002082), Depuy Spine, Inc.'s EXPEDIUM SFX Cross Connectors (K070300)

Intended Use / Indications for Use

The Facet-Link Stabilization Platform is intended to stabilize the spine as an aid to fusion through immobilization of the facet joints. The system is indicated for use with bone graft, at single or multiple levels, from C2 to S1 (inclusive) for the Facet Screws and L3 to S1 (inclusive) for MINI and HEMI devices. The Platform is indicated for the treatment of any or all of the following:

1. Spondylolisthesis.
2. Degenerative disc disease (DDD) as defined as back pain of discogenic origin as confirmed by radiographic studies.
3. Degeneration of the facets with instability.

The Facet-Link Facet Screw System is indicated for treatment of any or all of the following:

1. Pseudoarthrosis and failed previous fusion;

2. Spondylolisthesis; and

3. Degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies.

Device Description

The Facet-Link Stabilization Platform consists of a series of devices designed to stabilize the spine. The Platform includes the MINI and HEMI devices. The devices are secured to the bone using Facet-Link trans-articular (facet) screws. The MINI device utilizes an adjustable monorail to cross-connect the Facet Screws, while the HEMI device uses a small, fixed plate as a cross-connector. The implants are fabricated from anodized titanium alloy (Ti-6AI-4V) and are supplied in various sizes. The devices are provided non-sterile and for single patient use.

The Facet-Link Stabilization Platform requires several general purpose manual orthopedic instruments for implantation, including a variety of k-wires, gauges, inserters, drills, and drivers.

Technological Characteristics

The Stabilization Platform presents similar technological characteristics as compared to the predicate devices. The subject device and the predicate devices are available in various sizes and dimensions to accommodate individual patient anatomy. In addition, the indicated spinal levels for implantation for the Stabilization Platform devices are encompassed within the range for the predicate devices. Similar device components are included within the system, including screws plates, and/or connecting components. The Platform is composed of titanium alloy, comparable to the predicate devices. For all device systems, similar manual orthopedic instruments are used for implantation.

Performance Data

The following bench tests have been performed for the Facet-Link Stabilization Platform, in accordance with ASTM F1717, ASTM F1714, and ASTM F543:

- Static Axial Compression Bending
- Static Torsion
- Dynamic Axial Compression Bending

Functional cadaver tests were performed with implanted functional spinal units to demonstrate biomechanical performance under loading conditions. The biomechanical evaluations demonstrated that performance of the subject constructs was substantially equivalent to that of legally marketed screw constructs. Cadaver implantation testing was also conducted to assess the ability of users to perform the surgical technique successfully; results demonstrated that repeatable and proper seating of the devices was achieved. These tests demonstrated that the Stabilization Platform meets its intended performance specifications and is substantially equivalent to the predicate devices.

The materials of the Stabilization Platform are biocompatible for the indicated use in accordance with ISO 10993. The Facet-Link Stabilization Platform has also been evaluated in a magnetic resonance environment and testing demonstrated that the Stabilization Platform is MR Conditional, in

accordance with ASTM F2052-06.

Conclusions

The Facet-Link Stabilization Platform has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Facet-Link Stabilization Platform and its predicate devices do not raise any new issues of safety or effectiveness. Performance data demonstrate that the Facet-Link Stabilization Platform is substantially equivalent to its predicates.